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EXAMINER	
FLOOD, MICHELE C	

ART UNIT	PAPER NUMBER
1654	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/083,413	Domb et al.
Examiner	**Art Unit**
Michele Flood	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 25, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above, claim(s) *27-34* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-26* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group I, Claims 1-26, in Paper No. 6 is acknowledged. The traversal is on the grounds that the fields of search outlined by the Examiner for at least Groups I-III are substantially coextensive, and thus no additional searching burden would be placed on the Examiner. This is not found persuasive because the inventions of Groups I and II are unrelated. Firstly, while the invention of Group I is directed to a composition comprising (a) a therapeutically effective amount of at least one herbal or homeopathic active agent; and (b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition, the invention of Group II is directed to a composition comprising (i) a combination of an anti-inflammatory, anesthetic agent and an anti-microbial agent; and (ii) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition. Thus, the different groups comprise materially different ingredients. Secondly, the inventions of Groups I-II and III are related as process of making and product made; and, in the instant case, the process as claimed can be used to make other and materially different product, as evidenced by the claims themselves. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the

consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-11, 13-17, and 19-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claims 2 and 15 are rendered uncertain because the sentences lack a period; therefore, it is uncertain as to whether Applicant intends to direct the invention to further undisclosed limitations.

Regarding Claim 3, line 3, there is an apparent misspelling. Applicant may overcome the rejection by replacing "least1" with least 1.

Claim 4 recites the limitation "the herbal active agent" in line 1. The claim lacks clear antecedent basis for this limitation in the claim.

Claim 4, line 2, is rendered grammatically incorrect by "either". Applicant may overcome the rejection by deleting "either".

Claim 5 recites the limitation "the herb active agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the herb tincture" in line 1. There is insufficient antecedent basis for this limitation in the claim.

With regard to Claim 6, as drafted the recitation of the Markush group is improper because it recites both plants and herbal plants.

Claim 6, line 3, recites the abbreviation "Salvia offinc.". Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter.

Regarding Claim 6, line 3, there is an apparent misspelling. Applicant may overcome the rejection by replacing "Myrrah" with myrrh.

Regarding Claim 6, line 4, there is an apparent misspelling. Applicant may overcome the rejection by replacing "Phytolaca" with Phytolacca.

An apparent typographical error appears in Claim 6, line 6. Applicant may overcome the rejection by replacing the period ".", which appears after "Sage" with a comma.

With regard to Claim 6, line 7, the term "Propolis" renders the recitation of the Markush group improper because "Propolis" is not an herb, but a material derived from the hives of bees.

Regarding Claim 6, line 7, there is an apparent misspelling. Applicant may overcome the rejection by replacing "Barberine" with berberine.

Regarding Claim 6, line 8, there is an apparent misspelling. Applicant may overcome the rejection by replacing "berberidaccae" with Berberidaceae.

Claim recites the limitation "herb essential oils" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Regarding Claim 7, line 3, there is an apparent misspelling. Applicant may overcome the rejection by replacing "cedrwood" with cedarwood.

Regarding Claim 7, line 4, there is an apparent misspelling. Applicant may overcome the rejection by replacing "rosmarinus offencinalis" with *Rosmarinus officinalis*.

Regarding Claim 7, line 6, there is an apparent misspelling. Applicant may overcome the rejection by replacing "origano" with oregano, if appropriate.

Claim 8 recites the limitation "the essential oil" in line 1. The claim lacks clear antecedent basis for this limitation in the claim.

Claims 9 and 10 recite the limitation "said essential oil" in line 1. The claims lack clear antecedent basis for this limitation in the claims.

Claim 11 is rendered vague and indefinite by the term "pomella" because it is uncertain as to what is the meaning of "pomella". Perhaps, Applicant refers to 'pomelo' or grapefruit or *Citrus maxima*?

Claim 13, line 2, is rendered vague and indefinite by the phrase "in a synergistic and effective amount" because it is unclear as to what amount (e.g., amount range, proportion, and/or ratio) of each claimed ingredient actually define a synergistic amount with respect to the other ingredients so as to provide a combined synergistically effective amount of the overall composition. Accordingly, the metes and bounds of this phrase (e.g., the synergistically effective amounts of each ingredient with respect to the others) are not clearly nor adequately delineated with respect to the synergistic amounts of the individual components. Please note that synergism is an unpredictable phenomenon which is highly dependent upon specific proportions and/or amounts of particular ingredients. Accordingly, the recitations of the amounts ranges and/or proportions (e.g., ratios) of each claimed ingredient necessary to provide a synergistic combination is deemed essential (see, e.g., MPEP 2172.01) and, thus, should be defined in the independent claim language itself.

Claim 14 recites the limitation "the active composition" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "anesthetic agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 16 and 17 are rendered vague and indefinite by the phrase " and is in the form of the base or an acid-addition salt or both forms" because it is unclear as to what is the subject matter Applicant intends to direct the invention. The lack of clarity renders the claims ambiguous.

Claim 17 recites the limitation "the non-herbal agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "the active agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 19, the phrase "and the like" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "and the like"), thereby rendering the scope of the claim unascertainable.

Regarding Claims 11, 19 and 20, there is an apparent misspelling in line 1. Applicant may overcome the rejection by replacing "cirton" with citron.

Regarding claim 21, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The metes and bound of Claim 22 are made uncertain by the phrase "wherein the self-bioadhesive is a natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer and mixtures thereof" because the phrase is confusing. For instance, it would appear that the phrase refers to the "pharmaceutically acceptable solid bioadhesive carrier" instead of the "self-bioadhesive composition. Appropriate correction is required.

With regard to Claim 23, line 5, there is an apparent misspelling. Applicant may overcome the rejection by replacing "gaur-gum" with guar-gum.

Claim 24 recites the limitation the "adhesive" in line 2. The claim lacks clear antecedent basis for this limitation in the claim.

Claim 25 recites the limitation the "said enhancers" in line 1. There is insufficient antecedent basis for this limitation in the claim.

The metes and bounds of Claim 25 are made uncertain by "limonene derivatives" because it is unclear as to what constitutes "limonene derivatives" or how closely related the derivatives must be to considered derivatives of limonene. The lack of clarity makes the claim ambiguous.

Claim 26 is rendered vague and indefinite by "A composition according to claim 22 are polyacrylic acid polymers" because it is apparent that text has been omitted from the phrase. Thus, it is uncertain as to the subject matter Applicant intends to direct the invention.

Claim 26, line 2, recites the term "lightly crosslinked". The term "lightly crosslinked" in claim 26 is a relative term which renders the claim indefinite. The term "lightly crosslinked" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Objections

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in

independent form. As drafted, Claim 6 depends from Claim 3. However, it appears that Claim 6 should depend from Claim 5. For the purposes of examination, Claim 6 has been read as being properly dependent upon Claim 5.

Claims 20 and 21 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Specifically, Claims 20 and 21 fail to further the claimed invention because the claims are directed to "The active agent" instead of a composition.

Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. As drafted, Claim 25 depends from Claim 22. However, it appears that Claim 25 should depend from Claim 24. For the purpose of examination, Claim 25 has been read as being properly dependent upon Claim 24.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article (2) of such treaty in the English language.

Claims 1, 4, 5, 7, 15 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ronchi et al. (N).

Applicant claims a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue comprising (a) a therapeutically effective amount of at least one herbal or homeopathic active agent; and (b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 90 percent based on the weight of the whole composition. Applicant further claims a composition according to claim 1, wherein the herbal active agent is selected from the group consisting of an anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, and antiparasite agent, and combinations thereof. Applicant further claims a composition of claim 1, wherein the herb active agents are selected from the group consisting of bioactive herb extracts, tinctures, essential oils,

and mixtures thereof. Applicant further claims a composition of claim 5 wherein the herb essential oils active agents are selected from a recited Markush group, wherein pine oil is recited. Applicant further claims a composition of claim 1, further comprising a non-herbal active agent selected from a recited Markush group. Applicant further claims a composition of claim 1, wherein the self-bioadhesive is a natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer, and mixtures thereof. Applicant further claims a composition of claim 22, wherein said polyhydric polymer comprises at least one member selected from a recited Markush group. Applicant further claims a composition of claim 22 in the form of a tablet, wherein said adhesive additionally contains one or more members selected from a recited Markush group.

Ronchi teaches a solid, self-bioadhesive in the form of a lozenge composition for topical application that adheres to the oral mucosal tissue comprising at least one active ingredient in admixture with muco-adhesive polymers, and conventional carriers and excipients, on page 2, Column 2, lines 28-34. On page 3, Column 1, lines 4-13, Ronchi teaches that the muco-adhesive polymers (e.g., polycarbophil, polyacrylic acid derivatives and the salts thereof, vinylcarboxylic acid polymers and copolymers and the salts thereof, cellulose derivatives, etc.) can be used in an amount of .01 to 50%. The compositions taught by Ronchi comprise various active ingredients such as disinfectants and masking agents, e.g., saccharose, fructose, sorbitol, and xylitol (see page 3, Column 1, lines 24-44). In "Example 1", on page 2, Column 2, Ronchi teaches a

disinfectant sugar lozenge comprising Polycarbophil (Noveon® AA1), saccharose, glucose, menthol, eucalyptol, anethole, *Pumilius* pine essential oil, and peppermint oil.

The reference anticipates the claimed subject matter.

Claims 1, 4, 5, 7, 9, 19, 22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedman et al. (C, US 5,942,244) with evidence provided by Lawless (U).

Applicant's claimed invention was set forth above. Applicant further claims a composition according to claim 7, wherein said essential oil comprises at least one monoterpene with three unsaturations.

Friedman teaches a solid, self-bioadhesive composition for topical application in the form of a tablet comprising a therapeutically effective amount of an herbal medication and a polymeric matrix material, e.g., ethyl cellulose, a release enhancer and a filler. The herbal medication comprising the Friedman' composition include herbal extracts of Plantago, Hypericum, Echinacea, Baptisia, Calendula, Myrrh, Phytolacca, Salvia, Catechu black, Krameria, Tsuga, Rosmarinus, Styrax, Crataegus, Glycyrrhiza, Angelica, Krameria, Matricaria, Mallow and Sage; and essential oils such as cinnamon oil, cajeput oil, eucalyptus oil, fennel oil, geranium oil, lavender oil, lemon oil, spearmint oil, myrte oil, origano oil, pine oil, rosemary oil, sarriette oil, thyme oil, and tea-tree oil. Friedman also teaches that his composition comprises Propolis, a resinous substance found in beehives. See Column 2, lines 9-67. In Column 3, lines 50-67, under "EXAMPLE 3", Friedman teaches a tablet comprising 50% of ethyl cellulose, coffee

powder, and eucalypti oil. With regard to Claims 9 and 19, wherein Applicant claims that the composition consists of a mixture of natural monoterpenes with three unsaturations, the essential oil of eucalyptus comprising the composition taught by Friedman comprises the instantly claimed monoterpenes with three unsaturations because eucalyptus oil (depending upon the source of eucalyptus, see Blue gum eucalyptus on page 141 under 'Prinicipal Constituents') comprises terpinene, limonene and pinene, as evidenced by the teachings of Lawless. Please further note that the aforementioned secondary reference was only cited so as to show the inherent characteristics of eucalypti oil.

Friedman does not expressly teach his composition as a self-bioadhesive composition. However, the ingredients and the amounts of the ingredients taught by Friedman are the same as those instantly claimed; therefore, the functional effect or property must be the same. Moreover, Friedman teaches that the slow release tablets for oral administration permit a prolonged period of contact between the medication and the buccal and gingiva mucosa of the mouth, in Column 1, lines 6-10.

The reference anticipates the claimed subject matter.

Claims 1, 4, 5, 15-17, 22, 23 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Tapolsky et al. (A).

Applicant's invention of Claims 1, 4, 5, 15 and 22-23 was set forth above. Applicant further claims a composition of Claim 15, wherein the anesthetic agents is selected from a recited

Markush group. Applicant further claims a composition of Claim 15, wherein the non-herbal active agent is selected from a recited Markush group. It appears that Applicant further claims a composition according to claim 22, wherein said polyhydric acid polymer is a polyhydric acid polymer lightly crosslinked with a polyalkenyl polyether and cellulose derivative, and mixtures thereof.

Tapolsky teaches a solid, self-bioadhesive composition for topical application that adheres to the oral mucosal tissue comprising a therapeutically effective amount of at least one herbal active agent (e.g., thymol which is obtained from thyme oil and eugenol which is obtained from clove oil) and a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 5-95% by weight of the total composition, and wherein the bioadhesive comprises hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose. See claims 1, 10 and 11; and Column 6, lines 27-37. In Column 5, lines 31-58, Tapolsky teaches that the bioadhesive composition is in the form of a disk having two layers: an adhesive layer and a non-adhesive backing layer. The adhesive layer comprises a film forming polymer which may be crosslinked (see Column 5, lines 61-67; Column 6; and Column 7, lines 1-12). In Column 5, lines 16-30, Tapolsky teaches that the residence times which may be achieved for the referenced composition include 30 minutes to about 3 or about 4 hours. A preferred residence time for effective drug delivery is about 1 to 2 hours. In Column 7, line 13 bridging Column 8, lines 1-12, examples of pharmaceuticals which may be incorporated into the making of the referenced composition are taught, including inflammatory analgesic agents, steroidal anti-inflammatory

agents, antihistamines, local anesthetics, bactericides and disinfectants, vasoconstrictors, hemostatics, chemotherapeutic agents, antibiotics, keratolytics, cauterizing agents, and antiviral drugs. In Column 8, lines 25-32, Tapolsky teaches that the thickness of the composition may vary, depending on the thickness of each of the layers. Preferably, the bilayer thickness ranges from 0.05 to 1 mm. In Column 12, lines 66-67, disk having a ½ inch (12.7 mm) is taught by Tapolsky.

The reference anticipates the claimed subject matter.

Claims 1, 4-7, 9, 15-17, 19, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Roreger et al. (B) with evidence provided by Lawless (U).

Applicant's claimed invention of Claims 1, 4, 5, 15-17, 22 and 23 was set forth above. Applicant further claims the composition of claim 3, wherein the herb tincture active agents are selected from a recited Markush group. Applicant further claims a composition according to claim 7, wherein said essential oil comprises at least one monoterpene with three unsaturations. Applicant further claims a composition according to claim 4, wherein the active agent consists of three unsaturations comprising of: limonene, myrcene, pinenes, sabinene, terpinene, and the like.

Roreger teaches a hydrophilic, insoluble gel film for topical application that adheres to oral mucosal tissue comprising a therapeutically effective amount of at least one herbal, 0.05 to 30%-weight of at least one anionic water-soluble polymer, and 0.05 to 30%-weight of at least one cationic water-soluble polymer. In Column 2, lines 32 to Column 3, lines 1-15, Roreger

teaches polymers which can be used in the making of the referenced composition. In Column 10, lines 31-64, the gel film is taught as a carrier of therapeutics to the mouth or the mucous area of the mouth for the treatment of diseases and inflammation. Roreger teaches, in Column 10, lines 64 bridging Column 11, and Column 12, lines 1-27, various therapeutic agents (e.g., anesthetics, antiseptics, astringents, antibiotics, herbal extracts, and herbal essential oils). In Example 21, an insoluble gel film comprising myrrh tincture and sage tincture for application and adherence to the mucous membrane of the mouth is taught (see Column 15, lines 52 to Column 16, lines 1-4). In Example 24, an insoluble gel film for adherence to the skin comprising eucalyptus oil, drawf pine needle oil, anise oil is taught (see Column 16, lines 56-67 to Column 17, lines 1-14). With regard to Claims 9 and 19, wherein Applicant claims that the composition consists of a mixture of natural monoterpenes with three unsaturations, the essential oils of eucalyptus oil and dwarf pine needle oil comprising the composition taught by Roreger comprise the instantly claimed monoterpenes with three unsaturations because eucalyptus oil (depending upon the source of eucalyptus) comprises terpinene, limonene and pinene; and dwarf pine needle oil comprises limonene, pinene and myrcene as evidenced by the teachings of Lawless. Please further note that the aforementioned secondary reference was only cited so as to show the inherent characteristics of eucalyptus oil and pine oil.

It is noted that the second example (i.e., Example 24) taught by Roreger does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such

undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 15-17, 22, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapolsky et al. (A).

Applicant's claimed invention of Claims 1, 4, 5, 15-17, 22, 23 and 26 was set forth above. Applicant further claims a solid composition according to claim 1, wherein said composition is in the form of a disc of 2-15 mm diameter and 0.4 to 2.3 mm thick that adheres to oral mucosal tissue for at least 30 minutes. Applicant further claims a solid composition according to claim 1, wherein said composition is in the form of a disc of 5-11 mm diameter and 1 to 2 mm thick with tissue adherence of at least 1 hour.

The teachings of Tapolsky are set forth above. Tapolsky does not expressly teach a solid, self-bioadhesive composition comprising the instantly claimed measurements. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the thickness and the diameter of the composition taught by Tapolsky because Tapolsky teaches the requisite ingredients and amounts of ingredients, the residence times for effective drug delivery, and process steps for making the layers of the referenced composition, which can be used in the making of a disc having varying measurements of thickness and diameter. At the time the invention was made, one of ordinary skill in the art would have been motivated and one of ordinary skill in the art would have had a reasonable expectation to modify the measurements of the disc-shaped composition taught by Tapolsky to the instantly claimed measurements because Tapolsky teaches, in Column 8, lines 25-30, "The thickness of each layer may vary from 10 to 90% of the overall thickness of the bilayer device, and preferably varies from 30 to 60%." Thus, it would have been merely a matter of judicious selection to one of ordinary skill in the art at the time the invention was made to modify the combinations of the ingredients, the amounts of the ingredients, and the process steps for making the layers of the referenced composition in the making of the claimed composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to select result-effect amounts and degrees of thickness of the claimed ingredients to provide a composition with the claimed functional effect and claimed physical properties. Thus, it would appear that the claimed invention is no more than the routine optimization of result effect variables.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-11, 15-17, 19, 22, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapolsky et al. (A) in view of Iyer et al. (E) and Friedman et al. (D, US 6,197,305) with evidence provided by Lawless (U).

Applicant's claimed invention of Claims 1- 7, 9, 15-17, 22, 23 and 26 was set forth above. Applicant further claims the composition of claim 5, wherein the essential oil comprises at least one monoterpene with three unsaturations. Applicant further claims a composition according to claim 9, wherein said essential oil is a natural or synthetic mixture consisting of limonene, myrcene, a-pinene, b-pinene, sabinene characterized in that at least 60% by weight is limonene. Applicant further claims a composition according to claim 9, wherein said monoterpenes with three unsaturations is of citrus oil selected from the group consisting of lemon, pomella and citron.

The teachings of Tapolsky are set forth above. Tapolsky teaches the claimed invention except for wherein the herb tincture active agents are selected from the Markush group recited in Claim 6, wherein the herb essential oils active agents are selected from the Markush group recited in Claim 7, wherein the essential oil comprises at least one monoterpene with three unsaturations, wherein said essential oil is a natural or synthetic mixture consisting of limonene, myrcene, a-pinene, b-pinene, sabinene characterized in that at least 60% by weight is limonene,

and wherein said monoterpenes with three unsaturations is of citrus oil selected from the group consisting of lemon, pomella and citron. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instantly claimed ingredients having the instantly claimed biochemical properties to the composition taught by Tapolsky because Iyer teaches antimicrobial compositions which can be used in the making of oral compositions and Friedman teaches antifungal compositions which can be used in the making of oral compositions. Firstly, Iyer teaches antimicrobial compositions comprising at least two antimicrobial agents, agent A and agent B, which exhibit reduce MIC values relative to the MIC for the agents making up the combination measured alone. For example, in Column 3, lines 11-26, Iyer teaches that agent A and agent B are selected from the group consisting of berberine, cedarwood oil, chloramphenicol, citral, citronella oil, cocamidopropyl dimethylglycine, *Glycyrrhiza glabra* extract, hinokitol, juicy fruit basil oil, juniper berries oil, lemon basil oil, lemon oil, and *Rosmarinus officinalis* oil. The compositions taught by Iyer are useful as therapeutic agents such as in oral hygiene products. Secondly, Friedman teaches a combination of an herbal extract and an essential oil which exerts prolonged antifungal activity on mucosal membranes. The herbal extracts include material selected from the group consisting of Plantago, Hypericum, Echinacea, Baptisia, Calendula, Myrrah, Phytolocca, Salvia, Catechu black, Coneflower, Krameria, Tsuga, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Krameria, Matricaria, Mallow, Propolis (beehive material), and Sage; and the essential oils are selected from cinnamon oil, cajeput oil, citronella oil, eucalyptus oil, fennel oil, geranium oil, lavender

oil, lemon oil, spearmint oil, myrte oil, origano oil, pine oil, rosemary oil, sarriette oil, thyme oil, and tea-tree oil (see Column 1, lines 6-10; Column 2, lines 38-59; and claims). In Column 5, lines 9-39, Friedman further teaches that the herbal extracts are in the form of a tincture of botanical materials. In Figures 1 and 2, Friedman shows that the referenced compositions have prolonged activity against *Aspergillus niger* and *Candida albicans*. In Column 4, lines 18-37, Friedman teaches that the compositions can be used to combat fungal infection of mucosal organs and the oral cavity. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the instantly claimed ingredients having the instantly claimed biochemical properties to the composition taught by Tapolsky to provide the claimed invention because Iyer teaches that the antimicrobial compositions of his invention can be used in the making of therapeutic oral hygiene products for growth control of bacteria, such as *Actinomyces viscosus, Campylobacter rectus, Fusobacterium nucleatum, Porphyromonas gingivalis, Streptococcus mutans* and *Streptococcus mutans* (see Column 3, lines 28-38 and 47-51); and Friedman teaches that the compositions of his invention have strong antibacterial activity and anti-inflammatory activity in addition to its antifungal activity, can be used in the making of oral products, and can be used in the treatment of disease conditions such as *Herpes zoster* and *Herpes simplex* infections, dental ulcers, stomatitis, aphthous ulcers, and abscesses (see Column 4, lines 31-37; Column 8, lines 36-42; Column 9, lines 66-67 to Column 10, lines 1-4; and Column 10, lines 30-51). One of ordinary skill in the art at the time the invention was made would have been further motivated

and one would have had a high expectation of success to add the antimicrobial compositions taught by Iyer to the bioadhesive composition taught by Tapolsky to provide the claimed invention because Iyer teaches in Table 14 that the combination of the essential oil of lemon (which comprises 70% limonene, myrcene, pinenes and sabinene, as evidenced by the teaching of Lawless) in combination with an antimicrobial Agent B results in a significant decrease in the MIC value against various microorganisms which cause oral or periodontal disease. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-6, 12, 15-17, 22, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapolsky et al. (A) and Friedman et al. (D, US 6,197,6305) in view of Shuch et al. (F).

Applicant's claimed invention of Claims 1, 4-6, 11, 15-17, 22, 23 and 26 was set forth above. Applicant claims a composition according to claim 3 wherein the herb tincture active agents are selected from a recited Markush group. Applicant further claims a composition according to Claim 6 further comprising a salt selected from the group consisting of $MgBr_2$, NaCl, KCl and mixtures thereof.

The teachings of Tapolsky are set forth above. Tapolsky does not teach a solid, self-bioadhesive for topical application comprising herb tincture active agents selected from the recited Markush group of Claim 6, and further comprising a salt selected from the group consisting of $MgBr_2$, NaCl, KCL and mixtures thereof. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instantly claimed ingredients to the composition taught by Tapolsky because Friedman teaches antifungal compositions comprising botanical tinctures which can be used in the making of therapeutic oral compositions and Shuch teaches compositions comprising homeopathic salts and herbal botanicals which can be used in the making of therapeutic oral compositions. Firstly, Friedman teaches a combination of an herbal extract and an essential oil which exerts prolonged antifungal activity on mucosal membranes. The herbal extracts include material selected from the group consisting of Plantago, Hypericum, Echinacea, Baptisia, Calendula, Myrrh, Phytolocca, Salvia,

Catechu black, Coneflower, Krameria, Tsuga, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Krameria, Matricaria, Mallow, Propolis (beehive material), and Sage; and the essential oils are selected from cinnamon oil, cajeput oil, citronella oil, eucalyptus oil, fennel oil, geranium oil, lavender oil, lemon oil, spearmint oil, myrte oil, origano oil, pine oil, rosemary oil, sarriette oil, thyme oil, and tea-tree oil (see Column 1, lines 6-10; Column 2, lines 38-59; and claims). In Column 5, lines 9-39, Friedman further teaches that the herbal extracts are in the form of a tincture of botanical materials. In Figures 1 and 2, Friedman shows that the referenced compositions have prolonged activity against *Aspergillus niger* and *Candida albicans*. In Column 4, lines 18-37, Friedman teaches that the compositions can be used to combat fungal infection of mucosal organs and the oral cavity. Secondly, Shuch teaches a biologically absorbable dental composition comprising Vitamin C to promote healing of the mouth from gum disease and to reduce plaque build-up on the teeth; and coenzyme A-10 (ubiquinone) to enhance gum health. Other active agents comprising the composition taught by Shuch include Vitamin E; herbal extracts, e.g., Propolis, Echinacea, grape seed extracts, cranberry extract, stevia, tangerine oil, and lemon oil; and homeopathic tissue salts comprising potassium chloride and sodium chloride. See Column 2, lines 40-67, Column 3, and Column 4, lines 1-42. The formulation may be in the form of a dental prophylaxis paste (see Column 6, lines 64-67; and Examples 9-13, especially Examples 12 and 13, which comprise homeopathic salts). At the time the invention was made, one of ordinary skill in the art would have been motivated and one of ordinary skill in the art would have had a reasonable expectation of success to add the ingredients taught by

Friedman and Shuch to the composition taught by Tapolsky to provide the instantly claimed invention because Friedman teaches that the compositions of his invention have strong antibacterial activity and anti-inflammatory activity in addition to its antifungal activity, can be used in the making of oral products, and can be used in the treatment of disease conditions such as *Herpes zoster* and *Herpes simplex* infections, dental ulcers, stomatitis, aphthous ulcers, and abscesses (see Column 4, lines 31-37; Column 8, lines 36-42; Column 9, lines 66-67 to Column 10, lines 1-4; and Column 10, lines 30-51); and, Shuch suggests that the referenced composition comprising herbal ingredients and homeopathics act together to reduce and prevent major chronic diseases of the mouth and that the compositions can be incorporated into the making of a variety of delivery systems including resorbable membrane for application to gums and oral mucosa (see Column 1, lines 24-53 and Column 8, lines 50-60). Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

Michele C Flood

MCF

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